



February 6, 2024

VIA ELECTRONIC FILING — <http://www.regulations.gov>

Mojdeh Bahar
Associate Director for Innovation and Industry Services
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Re: Response to Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Docket No. 230831-0207)

Dear Associate Director Bahar:

Astellas Pharma US, Inc. (Astellas) appreciates the opportunity to submit comments to the National Institute of Standards and Technology (NIST) on its Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (the Draft Framework).¹ Astellas is a Japanese-based pharmaceutical company with its US headquarters in Northbrook, Illinois. Our more than 3,000 employees in the United States are dedicated to improving the health of individuals by developing and marketing treatments for unmet medical needs in the therapeutic areas of oncology, urology, cardiology, women’s health, infectious disease and immunology. Our comments focus on NIST’s proposal that agencies could consider the price of a product when determining whether to exercise march-in rights under the Bayh-Dole Act. Astellas strongly opposes NIST’s proposal.²

The Draft Framework details the factors that agencies may consider when deciding whether to exercise march-in rights and establishes a three-step process to guide the agency’s decision-making. Agencies are directed to consider “(1) whether Bayh-Dole applies to the invention(s) at issue; (2) whether any of the statutory criteria for exercising march-in applies under the circumstances; and (3) whether the exercise of march-in

¹ 88 Fed. Reg. 85593 (Dec. 8, 2023).

² The University and Small Business Patent Procedures Act of 1980 (the Bayh-Dole Act) granted federal agencies “march-in rights,” which permit agencies, in statutorily defined circumstances, to require licensing of a patent to an invention that was conceived or first actually reduced to practice under a federal funding agreement, or to grant a license of such a patent to themselves.



rights would support the policy and objectives of Bayh-Dole.”³ At Step 2, the Draft Framework includes price as a factor that agencies may consider when evaluating the first and second statutory march-in criteria. Criterion 1 of the Bayh-Dole Act requires an agency to consider whether “action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.”⁴ The Draft Framework would allow an agency, when evaluating whether criterion 1 has been met, to consider “factors that unreasonably limit availability of the invention to the public, including the reasonableness of the price and other terms at which the product is made available to end-users.”⁵

Criterion 2 of the Bayh-Dole Act requires an agency to consider whether “action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees.”⁶ The Draft Framework would allow an agency, when considering whether criterion 2 has been met, to consider whether:

the contractor or the licensee [is] exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances. . . [f]or example, has the contractor or licensee implemented a sudden, steep price increase in response to a disaster that is putting people’s health at risk?⁷

NIST states “that in reviewing this question, the agency is not limited to reviewing price increases; the initial price may also be considered if it appears that the price is extreme, unjustified and exploitative of a health or safety need.”⁸

At Step 3, when considering whether exercising march-in rights would support the policy and objective of Bayh-Dole, one factor agencies may consider is “[a]t what price would another licensee(s) be able to make the product available to the public?”⁹ It may be that NIST is suggesting that an agency could consider under Step 3 whether another company could offer the product at a lower price.

³ 88 Fed. Reg. at 85596.

⁴ 35 U.S.C. § 203(a)(1).

⁵ 88 Fed. Reg. at 85598.

⁶ 35 U.S.C. § 203(a)(2).

⁷ 88 Fed. Reg. at 85599.

⁸ *Id.*

⁹ *Id.* at 85600.



Astellas strongly opposes including price as a factor in all of the circumstances outlined above for the following reasons:

- Considering price as a march-in factor is inconsistent with the text of the Bayh-Dole Act and Congressional intent and prior National Institutes of Health (NIH) decisions interpreting the Act.
- If agencies were to consider price when deciding whether to exercise march-in rights, such an approach would have a chilling effect on collaboration and innovation, thus adversely affecting both the U.S. economy – including Americans’ jobs – and the health of many Americans who rely on advancements in medical technology to address their unmet health needs.

We are also incorporating by reference comments from our trade associations (PhRMA and the Chamber of Commerce).

I. Considering Price as a March-In Factor Departs from the Bayh-Dole Act’s Text and Purpose

Nowhere in the Bayh-Dole Act is “price” mentioned.¹⁰ The march-in rights provision specifies that agencies can exercise march-in rights in only four limited circumstances, none of which includes price or can reasonably be interpreted to permit consideration of a product’s price:

“(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive

¹⁰ 35 U.S.C. §§ 200-212.



right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.”¹¹

In response to assertions that price is a permissible factor, the lead authors of the Bayh-Dole Act – former senators Birch Bayh and Bob Dole – made clear that the omission of price from the statute was intentional. In a letter to the editor published in the *Washington Post*, Senators Bayh and Dole stated:

Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector. The purpose of our act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner. . .

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.¹²

A. Consideration of Price is Inconsistent with the Text of Criterion 1

Despite the fact that the Bayh-Dole Act does not include price, NIST improperly reads consideration of price into the statute under the first and second criteria for exercising march-in rights. NIST is incorrect in concluding that these criteria permit the consideration of price. Criterion 1 requires an agency to consider whether “action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.”¹³ “Practical application” is defined as the “means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits

¹¹ 35 U.S.C. § 203.

¹² Birch Bayh and Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, Wash. Post, Apr. 11, 2002, https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=lk_inline_manual_11 (emphasis added).

¹³ 35 U.S.C. § 203(a)(1).



are to the extent permitted by law or Government regulations available to the public on reasonable terms.”¹⁴

First, NIST incorrectly applies criterion 1 to licensees, stating that “if a contractor or licensee has stopped further work on the subject invention and the contractor and/or licensee has refused to restart work and rejects requests to license the subject inventions, that could suggest limited opportunities to commercialize the subject invention into new products.”¹⁵ As Norm Latker, former NIH patent counsel, stated in a 2004 public meeting addressing a petition to exercise march-in rights, criterion 1 only applies to contractors and assignees.¹⁶ And importantly, the fact that criterion 1 only applies to contractors and assignees demonstrates that the phrase “on reasonable terms” in the definition of “practical application” cannot mean “reasonable prices.”¹⁷ Latker explains:

Back in 1980, it was clear that most health inventions could only be practically developed under licenses with the drug industry. Bayh-Dole granted the property rights to the contractor, who would then negotiate a license agreement with the licensee. Of course, drug pricing played *no role* in these negotiations. Pricing a drug which has not yet been tested, approved and marketed is, of course, impossible.

As the phrase “reasonable terms” found in [criterion 1] applies to *contractors*, and not to *licensees*, it cannot mean “reasonable prices,” because contractors, in the view of the drafters, would not be setting prices.¹⁸ Additionally, the other criteria for exercising march-in rights make explicit reference to licensees.¹⁹ This omission shows that Congress intended not to apply the practical applicable basis for march-in to licensees. Further, the well-settled statutory canon *expressio unius est exclusio alterius* (“the express mention of one thing excludes all others”) underscores that the explicit references to “contractor or assignee” in Section 201(a)(1) excludes the application of this section to licensees, particularly when licensees are explicitly included in each of the other bases for march-in.

¹⁴ 35 U.S.C. § 201(f).

¹⁵ 88 Fed. Reg. at 85598 (emphasis added).

¹⁶ Norm J. Latker, Statement Before NIH on Essential Inventions Petition Regarding Norvir 5 (May 25, 2004), <https://www.techtransfer.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf>.

¹⁷ *Id.*

¹⁸ *Id.* (emphasis in original).

¹⁹ See 35 U.S.C. § 203(a)(2), (a)(3), and (a)(4).



Second, criterion 1 only requires that a contractor or assignee take or plan to take within a reasonable time “effective steps to achieve practical application.”²⁰ The NIH is the only agency that has issued decisions applying the practical application definition. NIH has consistently determined that the availability and public use of a product is sufficient to establish that “practical application” of the product has been achieved.²¹

NIH has repeatedly stated that “practical application is evidenced by the ‘manufacture, practice, and operation’ of the invention and the invention’s ‘availability to and use by the public.’”²² For instance, in 2016, NIH declined to exercise march-in rights with respect to the Astellas cancer drug XTANDI, finding that “Xtandi® is broadly available as a prescription drug” because “sales of [Xtandi®] increased 77% from Fiscal Year 2013 to Fiscal Year 2014 and are projected to increase 51% from Fiscal 2014 to Fiscal Year 2015.” NIH has never determined that price is an appropriate consideration when interpreting whether practical application has been achieved or in a march-in analysis more generally.

By a plain-text reading of the statute, price was not intended as a consideration to determine whether practical application had been achieved, and therefore, should not be included in the Draft Framework as a consideration for whether march-in rights should be exercised under criterion 1.

B. Consideration of Price is Inconsistent with the Text of Criterion 2

Furthermore, NIST is incorrect in concluding that criterion 2 permits the consideration of price. Criterion 2 requires an agency to consider whether “action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees.”²³ A health or safety need is not defined in the statute; and NIH is again the only agency that has considered whether a health or safety need has been reasonably satisfied in a march-in decision.²⁴ As with criterion 1, however,

²⁰ 35 U.S.C. § 203(a)(1).

²¹ NIH, Xtandi Decision (Mar. 21, 2023).

²² *Id.* See also NIH, Xtandi Decision (June 20, 2016); NIH, Norvir Decision (Nov. 1, 2013); NIH, Norvir Decision (July 29, 2004); NIH, Xalatan Decision (Sept. 17, 2004); NIH, CellPro Decision (Aug. 1, 1997).

²³ 35 U.S.C. § 203(a)(2).

²⁴ Even in instances in which petitioners have requested an agency other than NIH to exercise its march-in authority (e.g., in instances in which the relevant patents incorporate funding from multiple agencies), agencies have deferred to NIH to issue a decision. For instance, in 2016, petitioners requested NIH, the Department of Health and Human Services (HHS) more broadly, and the Department of Defense (DoD) consider exercising march-in rights on XTANDI. HHS and DoD deferred to NIH to issue the march-in decision. See Xtandi Decision 1 (June 20, 2016). In response to another XTANDI march-in petition sent to DoD in 2019 and HHS in 2021, HHS and DoD again deferred to NIH to issue a decision, culminating in NIH again declining to exercise march-in rights on XTANDI in 2023. See Xtandi Decision (Mar. 21, 2023).



consideration of price would read an element into criterion 2 that is beyond the plain meaning of the statutory criterion.

Additionally, NIH has not considered price when determining whether march-in is appropriate under criterion 2. Instead, for instance, NIH has found a health or safety need has been reasonably satisfied when there is no information to support that a drug is or will be in short supply. In 2016 when considering XTANDI, NIH found that petitioners “provide[d] no information and no information was identified from public sources to suggest that [Xtandi®] is currently or will be in short supply,”²⁵ and therefore, march-in rights were not justified under these circumstances.

NIH has also found that a health or safety need was reasonably satisfied when a drug was approved by the U.S. Food & Drug Administration as safe and effective or prescribed for its approved indications.²⁶ These considerations bear on the analysis for whether march-in rights are justified under criterion 2, but a product’s price does not. Therefore, price should be removed from the Draft Framework as a consideration under criterion 2.

C. NIH Has Repeatedly Recognized that the Bayh-Dole Act is Not a Price Control Tool

In the more than 40 years since the Bayh-Dole Act was passed, no agency has exercised march-in rights. NIH has repeatedly rejected calls to exercise march-in rights based on the price of a product.²⁷ In responding to a petition to exercise march-in rights with respect to AbbVie’s drug Norvir, NIH stated that it did “not think that the AbbVie pricing policies and pricing disparities between the United States and the other countries trigger any of the four Bayh-Dole march-in criteria.”²⁸

In addition, NIH has repeatedly stated that march-in is not an appropriate remedy for controlling prices and has called on Congress to address the issue of drug pricing legislatively. For example, in response to a petition to exercise march-in rights for Norvir, the NIH stated that “[t]he NIH continues to agree with the public testimony in 2004 that the extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients. . . [and] [a]s stated in previous march-in considerations, the general issue of drug pricing is appropriately addressed

²⁵ NIH, Xtandi Decision (June 20, 2016).

²⁶ See, e.g., NIH, Norvir Decision (Nov. 1, 2013); NIH, Norvir Decision (July 29, 2004).

²⁷ See, e.g., Lawrence A. Tabak, D.D.S., Ph.D., Performing the Duties of the NIH Director, Xtandi Decision (Mar. 21, 2023).

²⁸ NIH, Norvir Decision (Nov. 1, 2013).



through legislative and other remedies.”²⁹ Furthermore, in response to a petition regarding Xalatan, the NIH stated:

the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of whether drugs should be sold in the United States for the same price as they are sold in Canada and Europe has global implications and, thus, is appropriately left for Congress to address legislatively.³⁰

And in a Senate hearing, long-serving former NIH Director Francis Collins stated that “[t]he Bayh-Dole Act . . . does not appear to have really been designed to be utilized in a fashion where the price is the obstacle. It seems more to be a circumstance where the product was simply not available because it was not being commercialized and then NIH had the authority to step in and take over.”³¹

In our view, the statute is unambiguous that price is not a proper consideration when considering march-in rights,³² and therefore, the statute mandates adherence with an interpretation consistent with NIH’s longstanding view.³³ Further still, the Supreme Court has long noted that Congressional failure to amend a statute, notwithstanding a consistent construction by an agency with authority to enforce and interpret it, “creates a presumption in favor of the administrative interpretation, to which [the courts] should give great weight[.]”³⁴ Thus, the fact that Congress has not amended the Act in the wake of NIH decisions and public scrutiny with respect to the cost of prescription drugs suggests that Congress has ratified these decisions.

In sum, for decades, NIH has consistently interpreted the Act to *not* include price when considering exercising march-in under *any* of the criteria. It is therefore contrary to the Act’s language, Congressional intent, and agency interpretation to include price in the Draft Framework, and it should be removed from NIST’s guidance.

²⁹ *Id.*

³⁰ NIH, Xalatan Decision (Sept. 17, 2004).

³¹ Francis S. Collins, M.D., Ph.D., Director, NIH, Senate Hearing (Apr. 7, 2016).

³² See Letter from HHS Sec’y Burwell to Rep. Lloyd Doggett (dated Mar. 2, 2016) (“we believe the statutory criteria are sufficiently clear and additional guidance is not needed.”), <http://freepdfhosting.com/be7532cfc0.pdf>.

³³ See, e.g., *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446-47 (1987).

³⁴ *Costanzo v. Tillinghast*, 287 U.S. 341, 345 (1932); see also *CBS, Inc. v. FCC*, 453 U.S. 367, 382 (1981) (“We have held that ‘the construction of a statute by those charged with its execution should be followed unless there are compelling indications that it is wrong, especially when Congress has refused to alter the administrative construction.’” (quoting *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 381 (1969))).



II. Consideration of Price Would Chill Collaboration and Innovation and Could Negatively Impact the U.S. Economy and the Health of Americans

The Bayh-Dole Act fosters a delicate innovation ecosystem to guide early-stage discoveries into groundbreaking products across a number of industries including agriculture, advanced computing, energy, and life sciences. As it relates to the pharmaceutical industry, this ecosystem often requires the participation of university researchers, government agencies, innovative scientists at small biotechnology companies and pharmaceutical research companies who provide time, talent and resources – and often assume significant risk – with the hope of eventually commercializing an early-stage discovery.

Astellas' product XTANDI is a prime example of how this ecosystem resulted in a treatment now widely available to advanced prostate cancer patients in America. Although the U.S. government appears to have contributed less than \$500,000 to the initial discovery of the molecule that eventually became XTANDI, Astellas and its partners have invested more than \$2.3 billion to fund and conduct the extensive clinical trials and research necessary to demonstrate that XTANDI is safe and effective for patients, prepare and submit the applications that led to XTANDI's initial FDA approval in 2012 and three additional indications to benefit even more patients with advanced prostate cancer, and further understand which patients will benefit from treatment.³⁵ Astellas alone has invested nearly \$1.5 billion to date in research and development efforts for XTANDI to make it available to more patients who need it.³⁶

March-in rights may be invoked for a subject invention even when the U.S. government's contribution represents merely a fraction of the total amount of resources required to bring a product to market. Though the U.S. government often provides relatively small amounts of early concept funding, it is private collaborators, such as biopharmaceutical companies that invest the significant funding, time, and expertise necessary to bring a product to the market. Considering price when deciding whether to exercise march-in rights could upend this ecosystem that ensures the availability of these resources and have a chilling effect on collaboration and innovation. Indeed, a Government Accountability Office (GAO) report recognizes as much, noting that federal and technology transfer officials have identified four disincentives to the use of march-in

³⁵ Press Release, Astellas, Astellas Quote and Statement on the Bayh-Dole Act and XTANDI (April 20, 2023), <https://newsroom.astellas.us/Astellas-Quote-and-Statement-on-Bayh-Dole-Act-and-XTANDI-Updated-April-20,-2023>.

³⁶ *Id.*



authority, including a potential “chilling effect” on the commercialization of federal research efforts.³⁷

NIH’s previous attempt to control drug pricing through its agreements demonstrates the negative impact these restrictions have on collaboration and investment in innovation. From Fiscal Year (FY) 1990 to 1995, NIH sought to address concerns about high drug prices by adding a “reasonable pricing clause” to its cooperative research and development agreements (CRADAs).³⁸ “Under the clause, a company taking an exclusive license to bring an NIH invention to market could be compelled by the NIH to submit documentation showing a ‘reasonable relationship between the pricing of the product, the public investment in that product, and the health and safety needs of the public.’”³⁹ The NIH did not define “reasonable relationship.”⁴⁰ In FY 1996, NIH removed the reasonable pricing clause.⁴¹ NIH explained that it removed the clause because:

In the early 1990s, NIH leadership began to receive reports from companies and researchers about the negative impact of the reasonable pricing clause. NIH held two public meetings in 1994 with companies, patient advocates, and researchers, which came to a consensus that companies were avoiding collaborations with the NIH because of the pricing clause. As a result, the NIH Director announced in 1995 the removal of the clause from CRADAs and exclusive licenses.⁴²

Following the removal of the clause, there was a “large increase” in the number of CRADAs, which NIH concluded was “most likely was [due to] the removal of the reasonable pricing clause[.]”⁴³

Similar to when the “reasonable pricing clause” was in effect, if agencies were to consider price when determining whether to exercise march-in rights, companies would be hesitant to engage in collaborations with the government or to license early-stage inventions that are in need of further support for commercialization.

³⁷ GAO, GAO-09-742, *Information on the Government’s Right to Assert Ownership Control Over Federally Funded Inventions* 2, 14 (July 2009).

³⁸ NIH, *The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995 2*, <https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf>.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*



This chilling effect could cause a return to the time before the Bayh-Dole Act when publicly-funded inventions sat idle on the shelf instead of being commercialized for public use, negatively impacting both the U.S. economy and the health of Americans. Experts have stated that:

The commercialization system supported by Bayh-Dole is driven by small companies. They receive about 70% of university patent licenses and create more than half of new drugs developed in the U.S. These businesses “bet the farm” when trying to commercialize federally funded research. Allowing the government to march in because someone believes the price a company charges for its therapy isn’t “reasonable” — a completely undefined term — would be a devastating blow to the U.S. economy and the health of Americans.⁴⁴

In addition, recent research found that academic technology transfer supports as many as 6.5 million jobs.⁴⁵ And more than 200 drugs and vaccines were developed through public-private partnerships since the Bayh-Dole Act was enacted in 1980.⁴⁶ If agencies were to consider price, both jobs and the development of new drugs and vaccines would be at risk.

* * *

Astellas respectfully requests that NIST take these comments into consideration when developing the final framework document and remove price as a consideration from the framework. We would be happy to answer any questions that NIST may have regarding the topics we address herein.

Sincerely,

A handwritten signature in black ink that reads "Christie Bloomquist".

Christie Bloomquist,
Vice President, Government Affairs & Policy
Astellas Pharma US, Inc.

⁴⁴ Joseph Allen, *President Biden: Don't Misuse Bayh-Dole March-in Rights*, STAT, <https://www.statnews.com/2021/09/17/president-biden-dont-misuse-bayh-dole-march-in-rights/>.

⁴⁵ Association of University Technology Managers, *Driving the Innovation Economy: Academic Technology Transfer in Numbers*, <https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-2021.pdf>.

⁴⁶ *Id.*